

**Indiana State Department of Health
Health Care Regulatory Services**

**Medical Error Reporting Rule
LSA # 08-61**

**Summary of Public Comments
On the Proposed Rule and Recommendations
For the Final Rule**

September 2, 2008

To the ISDH Executive Board:

The Medical Error Reporting Rule was preliminary adopted by the Executive Board of the Indiana State Department of Health (ISDH) on May 12, 2008. A *Notice of Public Hearing* was published in the *Indiana Register* and a public hearing held on August 28, 2008.

During the comment period, the ISDH received oral and written comments on the proposed rule. The written and oral comments have been compiled into a Hearing Officer Report as an official record of the rule promulgation.

For this proposed rule, the ISDH only received one comment. The comment suggests two issues for consideration and review. The staff of the ISDH carefully reviewed and considered each comment. This document is a summary of comments received during the comment period and the recommendation of the staff regarding the comments. For brevity sake, the comments have usually been excerpted or paraphrased to the essential point. The source of the comment has been identified to assist the reader in referring back to the original.

Respectfully submitted,

Terry Whitson
Assistant Commissioner
Indiana State Department of Health

Summary and Review of Comments

Comments on 410 IAC 15-1.4-2.2(a)(1)(D)(vi): Stage 3 or Stage 4 Pressure Ulcers

The Indiana Hospital Association recommended a change in the pressure ulcer standard. The following is their proposed language: [Spencer Grove and Betsy Lee, Indiana Hospital Association, August 28, 2008]

“Stage 3 or 4 pressure ulcers acquired after admission to the hospital. Excluded are pressure ulcers identified as being present on admission at any stage or those identified as possible deep tissue injury (not associated with trauma) on admission or those unstageable because of the presence of eschar.

ISDH staff review and recommendation:

The current rule states: “Stage 3 or 4 pressure ulcers acquired after admission to the facility. Excluded is progression from a Stage 2 or Stage 3 pressure ulcer if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable due to the presence of eschar. The proposed language from the Indiana Hospital Association suggests two changes to the current rule.

1. The Indiana Hospital Association proposes a change that would exclude from reporting any pressure ulcer identified as being present on admission. In 2007 the National Quality Forum released its Consensus Report on Serious Reportable Events in Healthcare 2006 Update. The National Quality Forum did not change its standard relating to pressure ulcers. In its commentary, the National Quality Forum noted that members recognized the challenges involved in staging pressure ulcers but did not recommend exclusions.

The current ISDH rule follows the National Quality Forum consensus standards with one difference. In its consensus standard, the National Quality Forum does not exclude from reporting those pressure ulcers unstageable due to the presence of eschar. The ISDH includes that exception in the rule language. In theory, however, the eschar exception is consistent with National Quality Forum standard because the standard requires staging to determine whether it is reportable. Current medical education on ulcers indicates that eschar prevents staging. If a pressure ulcer is unstageable due to the presence of eschar, then the stage cannot be determined so the threshold for reporting would not be identified.

The proposed change suggested by the Indiana Hospital Association is a significant change to the National Quality Forum consensus standard. Under the proposed change, a pressure ulcer would be excluded from reporting, regardless of the stage that it becomes, if the pressure ulcer is identified upon admission. A stage one pressure ulcer identified upon admission to the facility therefore would not be reportable if it becomes a stage 3 or stage 4 pressure ulcer while the patient is admitted to the facility.

The ISDH staff does not recommend adoption of this proposed change. The National Quality Forum had extensive discussion on these standards by health care quality experts. The Forum acknowledges that a facility may not be able to eliminate all risk of these events. Including the event is intended to identify those events where there are preventative measures that can be taken to reduce the risk. The National Quality Forum

included in its standards those pressure ulcers that progress from a stage one to a stage 3 or 4 while admitted to a facility.

A stage one pressure ulcer is described by the American Medical Directors Association as “intact skin with nonblanchable redness of a localized area, usually over a bony prominence.” A stage one pressure ulcer is further described as indicating “at risk” persons. A stage two pressure ulcer is described as “partial thickness loss of dermis presenting as a shallow open ulcer with a red pink ulcer bed without slough” or “may also present as an intact or open/ruptured serum-filled blister. The position behind the standard is that, while a stage one may progress to a stage two even if identified, appropriate and timely identification and treatment should prevent progression to a stage 3 or 4.

The ISDH staff does not recommend adoption of this proposed change. The National Quality Forum had extensive debate on each proposed consensus standard. It appears appropriate in this situation to follow the consensus standard.

2. The Indiana Hospital Association proposes a change that would exclude pressure ulcers “identified as possible deep tissue injury (not associated with trauma) on admission.” Neither the National Quality Forum or ISDH rule define “pressure ulcer.” The term “pressure ulcer” has common medical meaning. A publication by the American Medical Directors Association distinguishes the various types of ulcers to include diabetic, ischemic, pressure, venous, trauma-caused, and dermatologic disease-caused. The Association refers to a pressure ulcer as “unrelieved pressure resulting in damage to skin or underlying tissue.” These other types of ulcers are not pressure ulcers.

In identifying the stages of a pressure ulcer, the Association identifies “suspected deep tissue injury” as the precursor to a stage one pressure ulcer. Pressure ulcers are essentially the result of deep tissue injury. A pressure ulcer begins with a situation or factors that result in deep tissue injury. Once it occurs, unrelieved pressure on that site is what progresses into a pressure ulcer.

Excluding pressure ulcers identified as possible deep tissue injury would essentially eliminate the reporting of pressure ulcers. Regardless of the underlying cause or condition, the pressure ulcer develops from deep tissue injury. All pressure ulcers originate with deep tissue injury so that standard would encompass all pressure ulcers. The proposed change appears to try to eliminate reporting of pressure ulcers within a subcategory of causes – perhaps external causes. Because the “cause” cannot usually be specifically identified or is a result of numerous contributing factors, the term “possibly” would likely eliminate any pressure ulcer from reporting.

The standard is intended to focus on unrelieved pressure. The underlying principle of the consensus standards is that a facility needs to identify areas with high pressure and areas with known deep tissue injury and take appropriate action to prevent development of a pressure ulcer. The reporting standard is significantly limited to stage 3 or 4 pressure ulcers.

The ISDH staff does not recommend adoption of this proposed change.